ONE STEP HAND SANITIZER - alcohol gel Belvedere International Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRUG FACTS

ETHYL ALCOHOL 62%

USE WHENEVER SOAP AND WATER ARE NOT AVAILABLE AND TO SUPPLEMENT ROUTINE HAND WASHING APPLY LIBERALLY TO HAND AND RUB THOROUGHLY UNTIL DRY

CHILDREN UNDER 6 YEARS OF AGE SHOULD BE SUPERVISED WHEN USING THIS PRODUCT, KEEP OUT OF REACH OF CHILDREN

ONE STEP 473mL

USE WHENEVER SOAP AND WATER ARE NOT AVAILABLE AND TO SUPPLEMENT ROUTINE HAND WASHING APPLY LIBERALLY TO HAND AND RUB THOROUGHLY UNTIL DRY

FOR EXTERNAL USE ONLY, KEEP OUT OF REACH OF CHILDREN, FLAMMABLE, AVOID CONTACT WITH EYES SHOULD THIS OCCUR FLUSH EYES WITH WATER DISCONTINUE USE IF IRRITATION DEVELOPS IF CONDITION PERSISTS FOR MORE THAN 72 HOURS CONSULT YOUR PHYSICIAN. IF SWALLOWED CONTACT A PHYSICIAN AS WELL. DO NOT STORE ABOVE 40 0 C/110 0 F

USE WHENEVER SOAP AND WATER ARE NOT AVAILABLE AND TO SUPPLEMENT ROUTINE HAND WASHING APPLY LIBERALLY TO HAND AND RUB THOROUGHLY UNTIL DRY

WATER, ISOPROPYL ALCOHOL, CARBOMER, ALOE VERA LEAF, POLYSORBATE 20



ONE STEP 473mL.jpg

ONE STEP HAND SANI	ΓIZER				
alcohol gel					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60742-47	NDC:60742-473	
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
Ingred	Basis of Stren	gth Stren	igth		
LCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL		62 mL in 10)0 mL		
Inactive Ingredients					
	Strength				
WATER (UNII: 059QF0KO0R)					
POLYSORBATE 20 (UNII: 7T1F30V5)	/H)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0)	X)				

CARBOMER 934 (UNII: Z1	35WT9208)						
Packaging							
# Item Code	Package Description	Marketing Start Date N		Marke	larketing End Date		
1 NDC:60742-473-01	473 mL in 1 BOTTLE, PUMP						
Marketing Information							
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		rketing End Date		
OTC monograph not final	part356		0 1/27/20 12				

Labeler - Belvedere International Inc. (247836356)

Establishment								
Name	Address	ID/FEI	Business Operations					
Belvedere International Inc.		247836356	manufacture					

Revised: 1/2012

Belvedere International Inc.